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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,204	11/20/2003	Jordon D. Honeck	P-20462.00	9800
27581	7590	05/03/2006		EXAMINER
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924				SMITH, STEPHANIE R
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/718,204	HONECK ET AL.	
	Examiner	Art Unit	
	Stephanie Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 November 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-48 is/are pending in the application.
 4a) Of the above claim(s) 17-29 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-16 and 30-48 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 20 November 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>23 April 2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16 and 30-48, drawn to a medical electrical lead, classified in class 607, subclass 122.
- II. Claims 17-29, drawn to a method of assembling a medical electrical lead, classified in class 29, subclass 746.

These claims are independent, each from the other, for the following reasons.

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make another and materially different product, such as one not requiring a coil that extends along a portion of the lead body, but instead requires a conductive wire or strand that extends along a portion of the lead body and that is held within the second groove.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with Michael Soldner on April 21, 2006, a provisional election was made without traverse to prosecute the invention of a medical electrical lead, claims 1-16 and 30-48. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-29 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 23, 2004 was filed after the mailing date of the application on November 20, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 6-10, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regards to claim 3, "lumen" is inferentially included. It is suggested to positively recite or functionally recite the lumen. If the Applicant wants to claim the lumen, it is suggested to first positively recite the lumen before it is used. If the lumen is being functionally recited it is suggested to use "for" or

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"adapted to..." Regarding claims 6-10, "is crimped..." and "is welded..." are vague and resemble a method step. It is unclear if a structure is being claimed. Regarding claim 32, "by means of a stamping process" is vague. It is unclear if this is invoking 112 6th paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-13, 15-16, 30-31, 33-41, 43, and 45-47 are rejected under 35 U.S.C. 102(b) as anticipated by Boser et al (U.S. 5676694). Referring to claims 1 and 30, Boser et al. teach an elongate lead body, a conductive coil, a conductive wire, and a conductive component with a first groove that holds the coil. The groove is attached to a crimp sleeve that is slid over and crimped to a conductor (see figures 1, 2, 4, 6-7, and 13 and column 1, lines 35-64). Because the definition of a groove is a long furrow or channel, the Examiner considers the conductive component to be part 315 (see figure 4), and the second groove is the channel that runs perpendicular to the first groove that contains the uninsulated part of the wire. In the alternative, the Examiner considers the conductive component to be part 312, and the second groove is again the channel that contains the uninsulated part of the wire. In a second alternative, the Examiner considers the second groove to be the "curved portion" of the underside of the

conductive component 315 holding the coil that is in contact with the crimping sleeve, which is crimped on the uninsulated portion of the wire, making an electrical connection between the coil and the wire (see figures 5-10). It is inherent to strip a wire, place the uninsulated portion of the wire into a crimping sleeve and crimp the crimping sleeve in order to provide an electrical connection between two components.

Regarding claims 2 and 31, Boser et al. teach that the sleeve protrudes from the groove (see figure 9). With reference to claim 3, Boser et al. disclose that the conductor extends within a lumen of the lead body, that the coil extends around an outer surface of the lead, that the first side of the crimp sleeve is within a lumen of the lead and the protruding surface extends through the lead (see figure 13). With reference to claims 4-5, Boser et al. teach the cable has a proximal and distal portion with an insulative outer layer (see figure 4 and column 4, lines 54-59). Regarding claims 6 and 7, Boser et al. do not teach a first sidewall and second sidewall explicitly, but instead teach an outer circumference of the sleeve, having a first sidewall and a second sidewall that each extend to the opposite side (see figure 9).

With regards to claims 9 and 10, Boser et al. teach that the portion of the coil includes a single filar that can be welded or compressed within the groove (see figures 6-7 and column 4, lines 60-64). With reference to claims 11, 12, and 36-38, Boser et al. teach that the groove can contain a plurality of filars that are welded or compressed within the grooves as described above (see figures 9 and 10). Referring to claim 13, Boser et al. teach that the coil forms a defibrillation electrode (see figure 4 and column 3, lines 55-56). Regarding claims 16 and 34, the component in which the groove is

formed is made of tantalum (see column 4, lines 35-37). With reference to claims 15, 33, 35, and 43, the grain orientation of the second groove is perpendicular to the first groove (see figures 4, 6-7, and 9-10). With reference to claims 39-41 and 45-47, the conductive component can be formed from platinum, stainless steel, or titanium (see column 4, lines 35-37). Claims 42 and 48 are considered to be product by process claims and therefore, the groove, the product, is being considered and the EDM process is not being considered. Further, Boser et al. teach the groove as described above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 8, 14, 32, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boser et al. Boser et al. disclose the claimed invention, but do not disclose expressly welding the wire within the groove, forming the conductive component of strip stock, and forming the second groove with a plurality of grooves, respectively. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the crimp sleeve with the two grooves as taught by Boser et al. with the welding the wire within the groove, forming the conductive component of strip stock, and forming the second groove with a plurality of grooves, respectively, because the Applicant has not disclosed that welding the wire within the groove, forming the conductive component of strip stock, and forming the second groove with a plurality of grooves, respectively, provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with crimping the conductor; forming the groove from tantalum, platinum, titanium, or stainless steel; a single groove for the second groove, respectively, as taught by Boser et al. because it secures the wire within the groove; the materials are biocompatible; and the single groove holds the wire, respectively, and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Boser et al. Therefore, it would have been an obvious matter of design choice to modify Boser et al. to obtain the invention as specified in the claims.

Further, Boser et al. disclose the claimed invention except for welding the wire within the groove, forming the conductive component of strip stock, and forming the

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second groove with a plurality of grooves, respectively. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical lead as taught by Boser et al, with welding the wire within the groove, forming the conductive component of strip stock, and forming the second groove with a plurality of grooves, respectively since it was well known in the art that welding the wire within the groove, forming the conductive component of strip stock, and forming the second groove with a plurality of grooves, respectively, secures the wire within the groove; the material is biocompatible; and the plurality of grooves secures the wire in multiple places, respectively.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. 6016436 to Bischoff et al. discloses an implantable electrical lead comprised of an outer coil held within a groove and a wire interconnected to the groove through a crimp sleeve.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Smith whose telephone number is 571-272-2834. The examiner can normally be reached on Monday-Friday between 7:30 am-4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SRS 4/28/06
SRS

GEORGE R. EVANISKO
PRIMARY EXAMINER

4/30/06